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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,375	11/09/2001	John Tallman	99,130-J	5633

7590

08/01/2005

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EXAMINER

BRANNOCK, MICHAEL T

ART UNIT

PAPER NUMBER

1649

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,375

Applicant(s)

TALLMAN ET AL.

Examiner

Michael Brannock

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1649

DETAILED ACTION

Status of Application: Claims and Amendments

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

Applicant's timely response of 5/2/05 to the Office action mailed 1/28/05 is noted. Applicant correctly points to the elected claims 36-47 which were incorrectly referred to in the prior Office action.

Response to Amendment

Applicant is notified that any outstanding objection or rejection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments and persuasive arguments regarding the rejection under 35 U.S.C. 103(a) citing Jensen-L, et al., WO 98/19165 in view of the Abstract of Calogero-AE et al, Brain Res 463(1)28-36, 1988, set forth previously.

Maintained Rejections:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-47 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent

No: 6444666 to Ladduwhetty et al. filed 8/27/1998.

Art Unit: 1649

The invention of the instant claims is predicated on the idea that selective activation GABA $\alpha_2 \beta\gamma_2$ or $\alpha_3 \beta\gamma_2$ receptors, while minimizing activation of receptors having α_1 subtype, will produce antidepressant effects with minimal sedative and cognitive impairing effects, see pages 33-39.

Patent No: 6444666 teach this principle with regard to anxiety and depression, see the see col 2, lines 10-26, and particularly lines 37-38. *In vivo* confirmation of the response sensitivity, e.g. claims 46 and 47, is also taught, see col 9, lines 1-5. These teaching differs from the instant claims in several insignificant ways. U.S. Patent No: 6444666 does not teach any particular EC_{50} , e.g. that the EC_{50} be less than 200 nM as in the instant claim 37. One of ordinary skill in the art of pharmacology would not need to be taught a particular number to use as this would readily be apparent during routine optimization of operating parameters.

Applicant argues that there is nothing in the cited reference or the prior art as a whole that suggest that an assay for anxiolytic compounds would also identify antidepressants. This argument has been fully considered but not deemed persuasive. This premise is not the basis of the rejection. Ladduwhetty do not teach that any assay for anxiolytics would identify antidepressants, they teach that particular assays that rely on selective activation GABA $\alpha_2 \beta\gamma_2$ or $\alpha_3 \beta\gamma_2$ receptors, while minimizing activation of receptors having α_1 subtype, will identify anxiolytics and antidepressants.

Applicant argues that Ladduwhetty does not teach this selectivity in the context of depression. This argument has been fully considered but not deemed persuasive. One of ordinary skill in the art appreciates that Ladduwhetty teaches the principle at col 2 lines 10-26 and then immediately provides examples, including depression, at lines 37-38. Furthermore,

Art Unit: 1649

Ladduwhetty distinctly state “such disorders include anxiety disorders,..., and depressive or bipolar disorder..”, see lines 30-36 of col 2.

Additionally, Applicant argues that the definition of the compounds referred to, e.g. at lines 37 and 38, is given later at col 3 lines 3-18 and encompasses compounds that are not selective. Applicant uses this argument as the basis for showing that 1) depression is not presented in the context of anxiety and 2) that Ladduwhetty appear to suggest that something other than selective activation of these subunits accounts for antidepressant activity. This argument has been fully considered but not deemed persuasive. Applicant’s interpretation of these teachings is unduly narrow and selective. As discussed above, one of ordinary skill in the art appreciates that Ladduwhetty teaches the principle of selective activation $\alpha_2 \beta\gamma_2$ and $\alpha_3 \beta\gamma_2$ subunits at col 2 lines 10-26 and then immediately provides examples where it is relevant, including depression, at lines 37-38 which, given even the most narrow possible reading of these teachings, would at least suggest to one of ordinary skill in the art that this principle applies to depression as well as anxiety. Furthermore, that the definition of “compounds of the invention” provided for in a separate section of the description includes compounds that do not display such specificity in no way contradicts the suggestion provided by col 2 that selective activation $\alpha_2 \beta\gamma_2$ and $\alpha_3 \beta\gamma_2$ subunits while minimizing α_1 subunit activation identifies antidepressants as well as anxiolytics with minimal sedative effects.

Applicant argues that the necessary connection between anxiolytic and antidepressants is simply not in the art. This argument has been fully considered but not deemed persuasive. As admitted by Applicant at page 10, last paragraph, the art recognizes overlap in the treatment of anxiety and depression, although it is agreed that the two disorders are distinct. Thus, one of

Art Unit: 1649

ordinary skill in the art would view the teachings of Ladduwhetty as describing a molecular underpinning of this overlap, i.e. that $\alpha_2 \beta\gamma_2$ and $\alpha_3 \beta\gamma_2$ are involved in both anxiety and depression.

Conclusion


Please note the new central fax number for official correspondence below:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867. Official papers filed by fax should be directed to **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB


July 25, 2005

Elizabeth C. Kemmerer

**ELIZABETH KEMMERER
PRIMARY EXAMINER**